

CA-ADAP Formulary Review: Respiratory Inhalers

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CA-ADAP Formulary Review: AGENDA

1 Disease State Overview

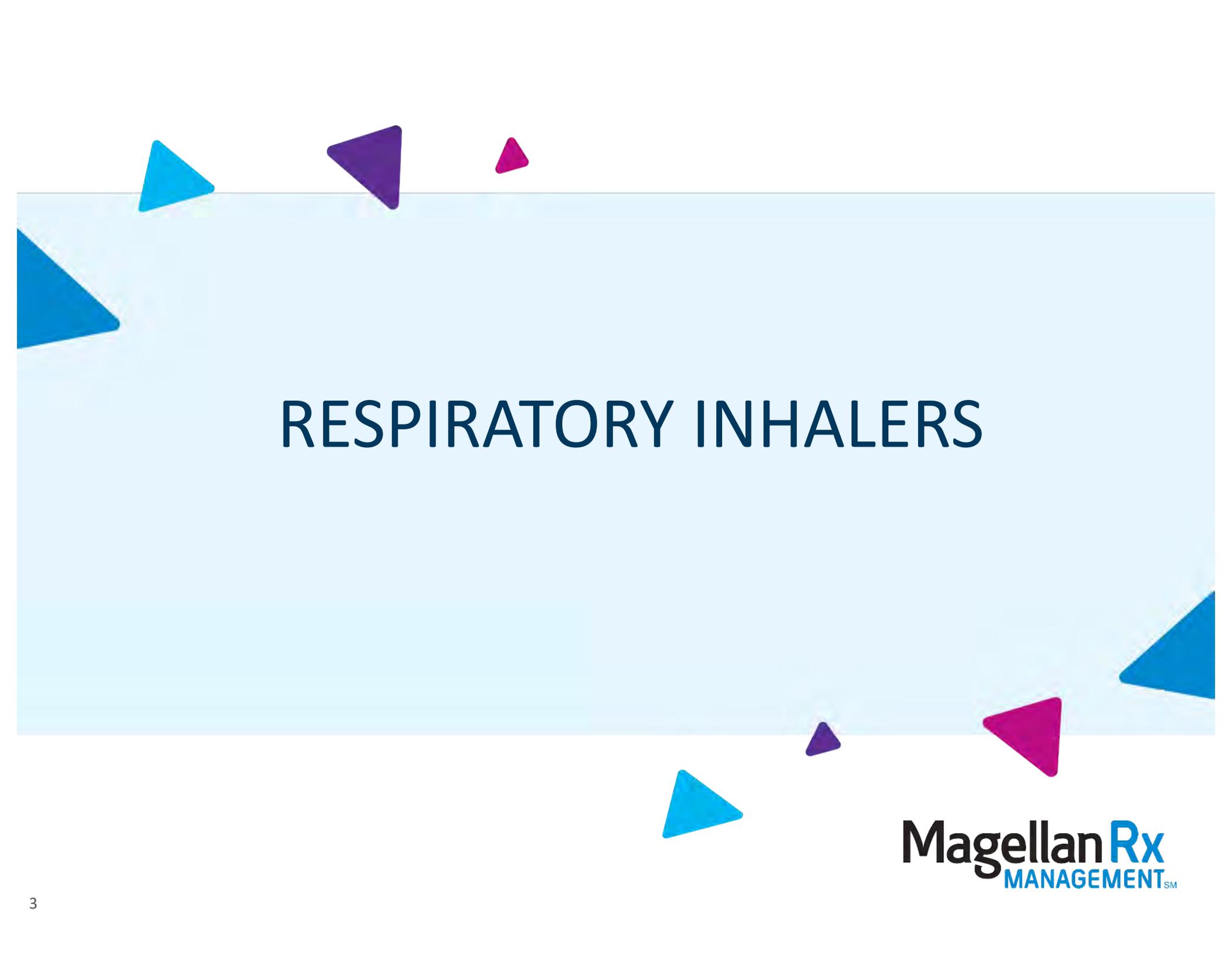
2 Medications

3 Denied claims data

4 Other ADAP formularies

5 Recommendations

6 Discussion

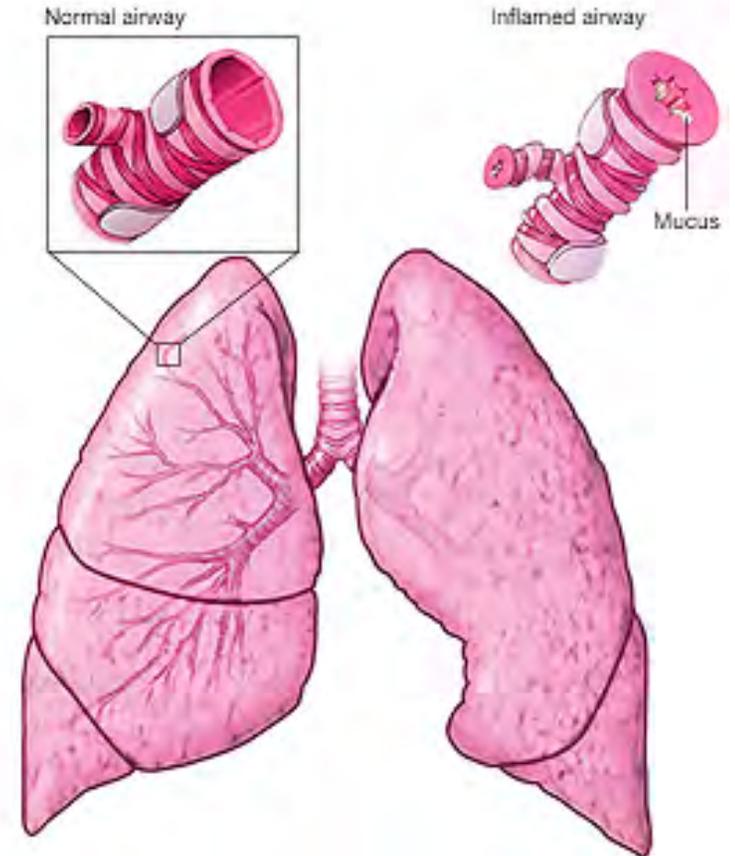


RESPIRATORY INHALERS

ASTHMA

- A chronic disease of the lungs:
 - Breathlessness
 - Chest tightness
 - Coughing
 - Wheezing
- May be a minor nuisance or life-threatening
 - 30-37% w/acute asthma
 - 16% near-fatal asthma
 - 15-27% dying of asthma

Had symptoms less than weekly in the previous 3 months
- Triggers vary from person to person:
 - Air pollutants
 - Certain medications
 - Physical activity
 - Pollen, dust mites, pet dander
 - Respiratory infections
- PLWH are at an increased risk for having Asthma:
 - HIV infection is associated with a high prevalence of respiratory symptoms



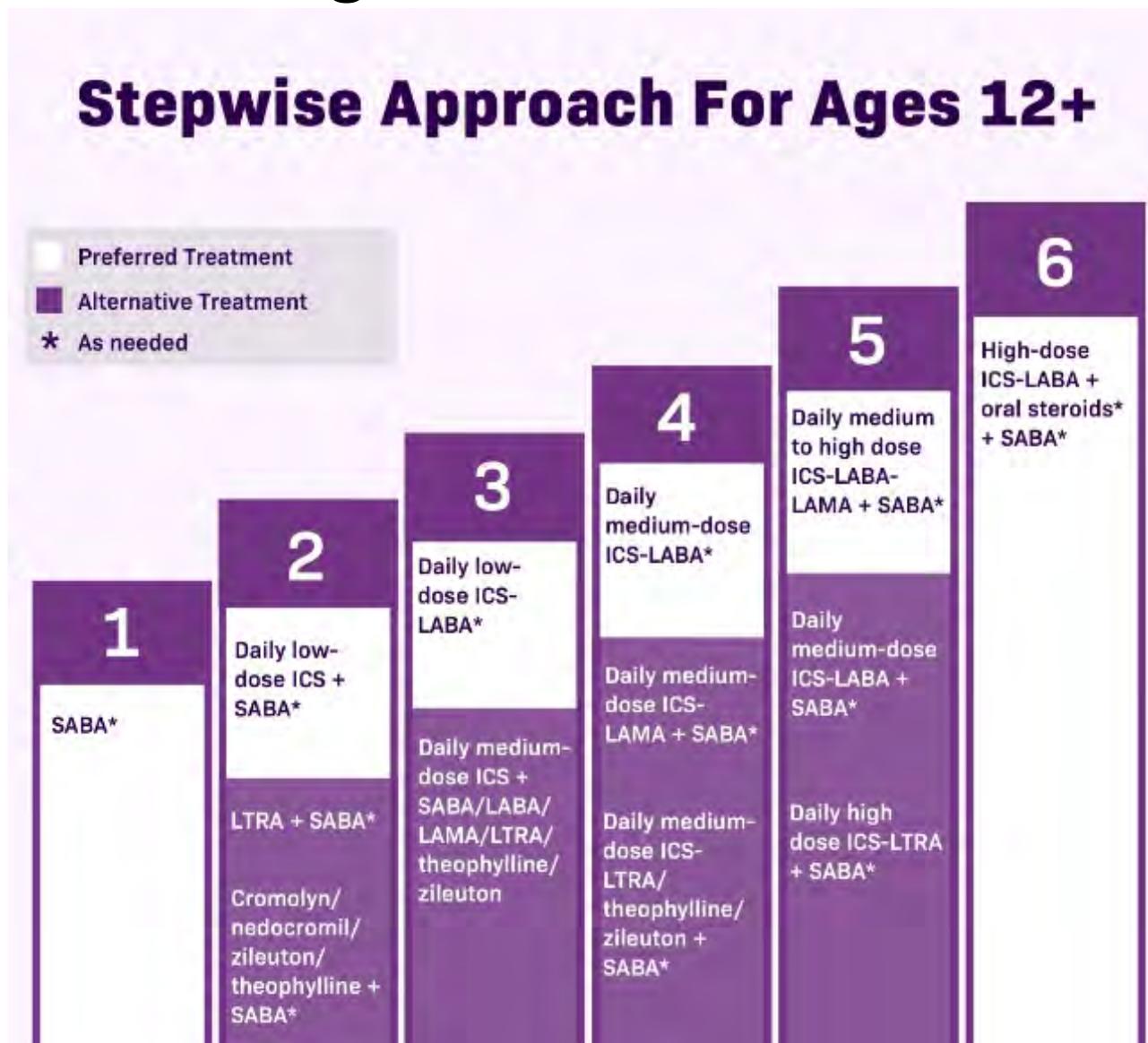
ASTHMA cont'd



- Consequences of uncontrolled asthma:
 - Frequent MD visits
 - Sick days from school/work
 - Hospitalizations
 - Premature death
- Asthma cannot be cured, but symptoms can be controlled
- Goals of treatment:
 - Prevention of symptoms
 - Maintain (near) normal lung function and normal activity levels
 - Require infrequent use of short-acting beta₂-agonists (SABA)
 - Reduce risk of exacerbations
 - Identify and avoid triggers
 - Minimize need for emergency care, hospitalization
 - Prevent loss of lung function
 - Minimize adverse effects of therapy



Asthma Management - NAEPP

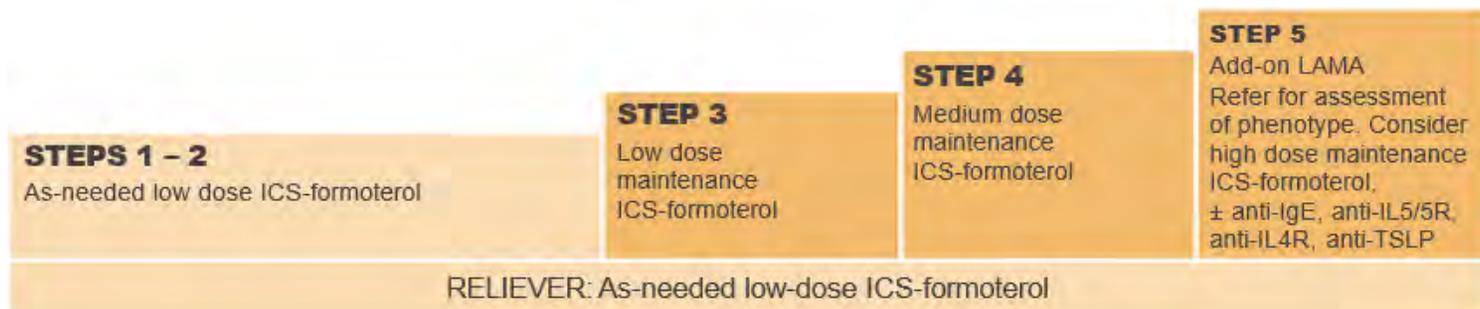


ICS = inhaled corticosteroid; LABA = long-acting beta2-agonist; LAMA = long-acting muscarinic antagonist; LTRA = leukotriene receptor antagonist; SABA = inhaled short-acting beta2-agonist

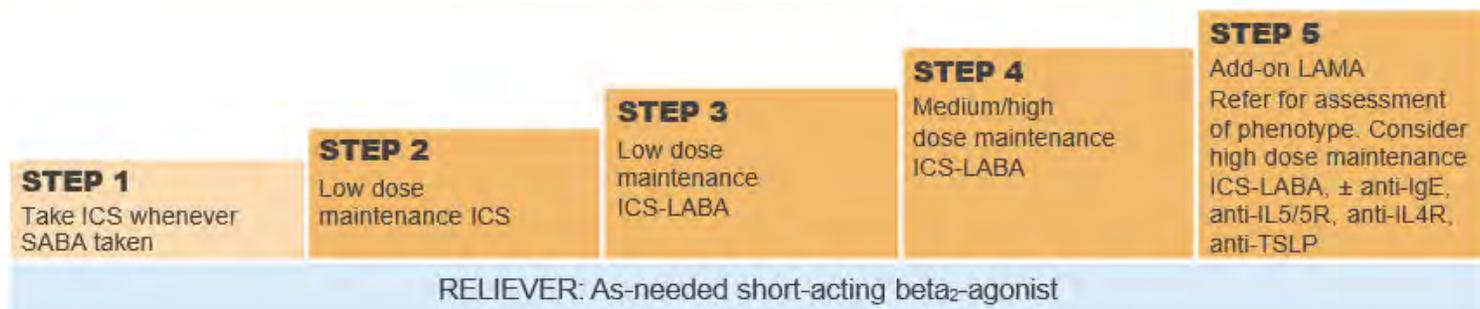
Asthma Management – GINA Report



CONTROLLER and PREFERRED RELIEVER (Track 1). Using ICS-formoterol as reliever reduces the risk of exacerbations compared with using a SABA reliever



CONTROLLER and ALTERNATIVE RELIEVER (Track 2). Before considering a regimen with SABA reliever, check if the patient is likely to be adherent with daily controller



Other controller options for either track (limited indications, or less evidence for efficacy or safety)

	Low dose ICS whenever SABA taken, or daily LTRA, or add HDM SLIT	Medium dose ICS, or add LTRA, or add HDM SLIT	Add LAMA or LTRA or HDM SLIT, or switch to high dose ICS	Add azithromycin (adults) or LTRA. As last resort consider adding low dose OCS but consider side-effects
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ICS = inhaled corticosteroid; LABA = long-acting beta2-agonist; LAMA = long-acting muscarinic antagonist; LTRA = leukotriene receptor antagonist; SABA = inhaled short-acting beta2-agonist; anti-IgE = monoclonal antibody that targets IgE; anti-IL5/5R = monoclonal antibody that targets IL-5 or its receptor IL-5R; anti-IL4R = monoclonal antibody that targets IL-4R cytokine; anti-TSLP = monoclonal antibody that targets TSLP cytokine

Asthma Treatment: SABAs



- **Inhaled Short-Acting Beta₂-Agonists (SABAs):** Provide quick relief for asthma symptoms.
 - **Place in therapy:**
 - Considered preferred treatment to relieve acute bronchospasm according to the NAEPP
 - Used in persistent asthma for acute symptom control
 - If used > twice a week or if significant symptoms recur, additional therapy should be added
 - **Recommend adding albuterol MDI to the formulary**

Agent	Generic	Denials Oct 2021-Sep 2022	AZ	CA	FL	NY	TX	WA	Comments
ALBUTEROL HFA (ProairHFA, ProventilHFA, VentolinHFA)	X	88.9%	X	X	X	X			<ul style="list-style-type: none"> • 90 mcg Inhaler • Recommend adding
ALBUTEROL (Proair Digihaler, Proair Respiclick)		2.38%	X	X	X	X			<ul style="list-style-type: none"> • 90 mcg Inhaler
ALBUTEROL Nebulizer Solution	X	7.54%			X				<ul style="list-style-type: none"> • 2.5 mg/0.5 ml solution, 5 mg/ml solution, 0.63 mg/3 ml solution, 1.25 mg/3 ml solution, 2.5 mg/3 ml solution
LEVALBUTEROL HFA (Xopenex)	X	1.15%							<ul style="list-style-type: none"> • 45 mcg HFA Inhaler
LEVALBUTEROL Nebulizer Solution (Xopenex)	X	-							<ul style="list-style-type: none"> • 0.31mg/3mL solution, 0.63mg/3mL solution, 1.25mg/3mL solution, 1.25mg/0.5mL solution

Asthma Treatment: ICS



- **Inhaled Corticosteroids (ICS):** are considered the most effective long-term usage therapy for control and management of asthma.
 - **Place in therapy:** first line therapy for all patients with persistent asthma to control asthma symptoms and prevent exacerbations according to the NAEPP.
 - Suppress inflammation in airways and make airways less sensitive.
 - **Recommend adding at least one ICS to the formulary**

Agent	Generic	Denials Oct 2021-Sep 2022	AZ	CT	FL	NY	TX	WA	Comments
BECLOMETHASONE (QVAR)		21.6%	X		X	X			<ul style="list-style-type: none"> • 40 and 80 mcg Redihaler • Dosing 40-320 mcg BID • No D/D Interactions with ART • Recommend adding
BUDESONIDE (Pulmicort)	X*	14.4%							<ul style="list-style-type: none"> • 90mcg, 180mcg inhaler • Inhalation solution: 1mg/2mL, 0.25mg/2mL, 0.5mg/2mL • *Pulmicort Flexhaler not avail as generic
CICLESONIDE (Alvesco)		35.2%							<ul style="list-style-type: none"> • 80 and 160 mcg inhaler • Dosing 80-160 mcg BID
FLUTICASONE (Armonair Digihaler, Arnuity Ellipta, Flovent)	X*	24.4%		X		X			<ul style="list-style-type: none"> • Dosing varies • *Flovent avail as generic
MOMETASONE (Asmanex)		4.4%							<ul style="list-style-type: none"> • HFA= 50mcg, 100 mcg, and 200 mcg • Twisthaler 110 mcg and 220 mcg • Dosing up to 800 mcg/day

Asthma Treatment: LABAs



- **Inhaled Long-Acting Beta₂-Agonists (LABAs):** used ONLY in conjunction with an inhaled corticosteroid in asthma therapy.
 - **Place in therapy:** used as additional therapy to an inhaled corticosteroid in patients with persistent asthma.
 - Not used as monotherapy.

Recommend adding at least one LABA/ICS agent to the formulary

Agent	Generic	Denials Oct 2021-Sep 2022	AZ	CT	FL	NY	TX	WA	Comments
BUDESONIDE/FORMOTEROL (Symbicort)	X	23.93%	X		X	X			<ul style="list-style-type: none"> • 80/4.5 and 160/4.5 • Both dosed 2 puffs BID • Recommend adding
FLUTICASONE/SALMETEROL (Advair, Airduo)	X	44.6%	X	X					<ul style="list-style-type: none"> • Advair:Diskus 100-50, 250-50, 500-50, HFA 45/21, 115/21, 230/21 • Airduo: Digihaler and Respiclick 55-14mcg, 113-14mcg, 232-14mcg; • Recommend adding *Diskus generic
FLUTICASONE/UMECLIDIN/VILANTEROL (Trelegy Ellipta)		10.14%							<ul style="list-style-type: none"> • 100-62.5-25, 200-625-25
FLUTICASONE/VILANTEROL (Breo Ellipta)	X	13.26%							<ul style="list-style-type: none"> • 100-25mcg, 200-25mcg
MOMETASONE/FORMOTEROL (Dulera)		6.63%							<ul style="list-style-type: none"> • 50-5mcg, 100-5mcg, and 200-5mcg • Both dosed 2 inhalations BID
SALMETEROL (Serevent Diskus)		1.43%		X		X			<ul style="list-style-type: none"> • LABA single agent product • 1 inhalation Q12 hr

Asthma Treatment: LAMAs



- **Long-Acting Muscarinic Antagonists (LAMAs):** To be used in combination with ICS
 - **Place in therapy:** Used as alternative therapy when daily + PRN ICS-formoterol is not effective in Steps 3 & 4

Consider adding to the formulary

Agent	Generic	AZ	CT	FL	NY	TX	WA	Comments
TIOTROPIUM (Spiriva Respimat)		X			X			• 1.25mcg, 2.5mcg Respimat

Asthma Treatment – Oral Therapy



- **Leukotriene Modifiers**: Block the actions of inflammatory leukotrienes that lead to airway tightening and production of excess mucus and fluid

Recommend adding at least one to the formulary

Agent	Generic	# Unique Cardholder ID Denials Oct 2021-Sep 2022	AZ	C T	FL	NY	T X	WA	Comments
MONTELUKAST (Singulair)	X	99.24%	X		X	X			<ul style="list-style-type: none"> • 10mg oral tablet • Dosing is 10 mg tab PO QHS • Recommend adding to the formulary
ZAFIRLUKAST (Accolate)	X	0.76%					X		<ul style="list-style-type: none"> • 10 or 20 mg oral tablet • Dosing is 20 mg tablet PO BID
ZILEUTON (Zyflo)	X	-					X		<ul style="list-style-type: none"> • 600mg oral tablet

Formulary Management

Recommendations: Asthma Treatment



1

Inhaled SABA
(Albuterol MDI)

Recommend addition to the ADAP
formulary.

2

Inhaled Corticosteroid
(QVAR)

Recommend addition to the ADAP
formulary.

3

Inhaled LABA/ICS
(Advair Diskus &
Symbicort)

Recommend addition to the ADAP
formulary.

4

Inhaled LAMA (Spiriva)

Recommend addition to the ADAP
formulary.

Formulary Management

Recommendations: Asthma Treatment cont'd



5

Leukotriene Modifiers
(Singulair)

Recommend addition to the ADAP
formulary.

Chronic Obstructive Pulmonary Disease (COPD)



- A group of diseases causing airflow blockage and breathing-related problems

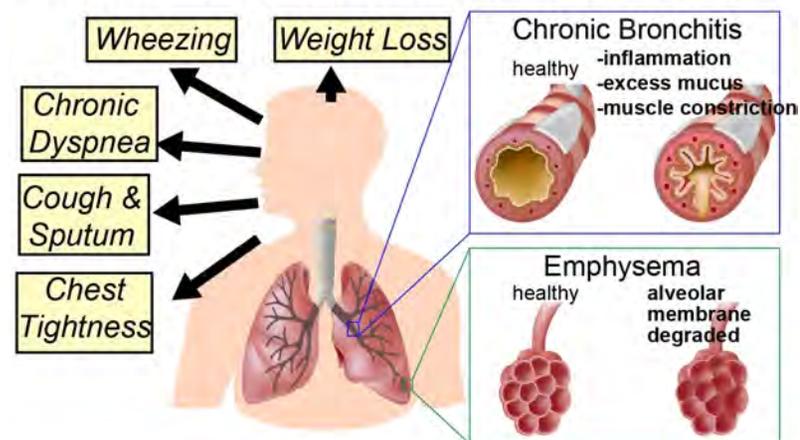
- Symptoms:

- Excess phlegm/mucus
- Frequent coughing or wheezing
- SOB
- Trouble taking deep breath

- Repercussions:

- Death
- Depression
- ER/hospital visits
- Increased confusion/memory loss
- Increased risk of heart attack
- Limitations on activity
- Unable to work

Chronic Obstructive Pulmonary Disease



- 15.7 million people in the US have COPD
- COPD is the 4th leading cause of death in the US
- One of the most common chronic diseases in PLWH

COPD Treatment: SABAs



- Inhaled Short-Acting Beta₂-Agonists (SABAs): Provide quick relief of symptoms
- Place in therapy:
 - Regular and as-needed use improves FEV1 and symptoms
 - GOLD guidelines recommend use in combination with SAMA for first line therapy

Recommend adding albuterol MDI to the formulary

Agent	Generic	Denials Oct 2021-Sep 2022	AZ	CT	FL	NY	TX	WA	Comments
ALBUTEROL HFA (ProairHFA, ProventilHFA, VentolinHFA)	X	88.92%	X	X	X	X			<ul style="list-style-type: none"> • 90 mcg Inhaler • Recommend adding
ALBUTEROL (Proair Digihaler, Proair Respiclick)		2.38%	X	X	X	X			<ul style="list-style-type: none"> • 90 mcg Inhaler
ALBUTEROL Nebulizer Solution	X	7.54%			X				<ul style="list-style-type: none"> • 2.5 mg/0.5 ml solution, 5 mg/ml solution, 0.63 mg/3 ml solution, 1.25 mg/3 ml solution, 2.5 mg/3 ml solution
LEVALBUTEROL HFA (Xopenex)	X	1.15%							<ul style="list-style-type: none"> • 45 mcg HFA Inhaler
LEVALBUTEROL Nebulizer Solution (Xopenex)	X	-							<ul style="list-style-type: none"> • 0.31mg/3mL solution, 0.63mg/3mL solution, 1.25mg/3mL solution, 1.25mg/0.5mL solution

COPD Treatment: LABAs



- **Inhaled Long-Acting Beta₂-Agonists (LABAs):** Duration of action is 12 or more hours
 - **Place in therapy:** maintenance therapy in patients who are symptomatic despite SABA use
 - GOLD guidelines recommend use in combination with LAMA for second line therapy
 - Not used as monotherapy.

Recommend adding at least one LABA/ICS agent to the formulary

Agent	Generic	Denials Oct 2021-Sep 2022	AZ	CT	FL	NY	TX	W A	Comments
FORMOTEROL/BUDESONIDE (Symbicort)		25.14%	X		X	X			<ul style="list-style-type: none"> • 80/4.5 and 160/4.5 • Both dosed 2 puffs BID • Recommend adding
FORMOTEROL/GLYCOPYROLATE/ BUDESONIDE (Breztri Aerosphere)		1.91%							<ul style="list-style-type: none"> • 160mcg-9mcg-4.8mcg
SALMETEROL (Serevent Diskus)		1.5%		X		X			<ul style="list-style-type: none"> • LABA single agent product • 1 inhalation BID
SALMETEROL/FLUTICASONE (Advair)	X	46.86%	X	X					<ul style="list-style-type: none"> • Diskus 100-50, 250-50, 500-50, HFA 45/21, 115/21, 230/21 • Recommend adding
VILANTEROL/FLUTICASONE (Breo Ellipta)		13.93%							<ul style="list-style-type: none"> • COPD maintenance therapy and exacerbation reduction
VILANTEROL/UMECLIDIN/ FLUTICASONE (Trelegy Ellipta)		10.66%							<ul style="list-style-type: none"> • 100-62.5-25, 200-625-25

COPD Treatment: SAMAs



- **Inhaled Short-Acting Antimuscarinic Agents (SAMAs)**: block the M2 receptor that causes bronchoconstriction in the airway.
 - **Place in therapy**: may be used for first-line therapy in patients with mild, stable COPD
 - GOLD guidelines recommend use in combination with SABA for first line therapy
 - Also used for the treatment of asthma acute exacerbation
- Recommend adding to the formulary*

Agent	Generic	AZ	CT	FL	NY	TX	WA	Comments
IPRATROPIUM (Atrovent)		X		X	X			<ul style="list-style-type: none"> • Duration of action is 6-8 hours • 2 puffs TID or QID • 17 mcg MDI • <i>Recommend adding</i>

COPD Treatment: LAMAs



- **Inhaled Long-Acting Antimuscarinic Agent (LAMA):** prolonged binding to muscarinic receptors M₃ to prolong the duration of the bronchodilator effect
 - **Place in therapy:** used as maintenance therapy in patients who are symptomatic despite SABA use.
 - Triple inhaled therapy of LABA/LAMA/ICS improves lung function, symptoms, and health status compared to dual therapy

Recommend adding to the formulary

Agent	Generic	Denials Oct 2021-Sep 2022	AZ	CT	FL	NY	TX	WA	Comments
ACLIDINIUM (Tudorza Pressair)		12.82%							<ul style="list-style-type: none"> • 400 mcg Inhalation powder • 1 puff BID • Duration of action 12-24 hours
GLYCOPYRROLATE (Lonhala Inhalation Solution)		-							<ul style="list-style-type: none"> • 25 mcg
REVEFENACIN (Yupelri Inhalation Solution)		-							<ul style="list-style-type: none"> • 175mcg/3mL
TIOTROPIUM (Spiriva Respimat, Spiriva HandiHaler)						X			<ul style="list-style-type: none"> • 18 mcg inhalation powder= 2 inhalations from one capsule QD • 2.5 mcg inhalation solution=2 puffs QD • Duration of action is 24 hours • Recommend adding
UMECLIDIINIUM (Incruse Ellipta)		87.18%							<ul style="list-style-type: none"> • 62.5 mcg powder for inhalation • 1 puff QD • Duration of action is 24 hours
UMECLIDIINIUM/VILANTEROL (Anoro Ellipta)									<ul style="list-style-type: none"> • COPD maintenance therapy • Combination of LAMA/LABA

Formulary Management Recommendations: COPD Treatment



1 Inhaled SABA
(Albuterol MDI)

Recommend addition to the ADAP
formulary.

2 Inhaled LABA (Advair
Diskus)

Recommend addition to the ADAP
formulary.

3 Inhaled SAMA (Atrovent)

Recommend addition to the ADAP
formulary.

4 Inhaled LAMA (Spiriva)

Recommend addition to the ADAP
formulary.

References



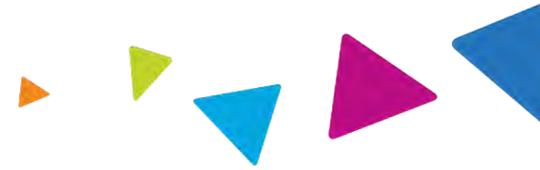
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